UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	6

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/436,348	Grillo-Lopez et al.
Examiner	**Group Art Unit**
Ron Schwadron, Ph.D.	1644

Responsive to communication(s) filed on _____ .

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

X Claim(s) 1-6 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

X Claim(s) 1-6 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

X Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

X Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- *SEE OFFICE ACTION ON THE FOLLOWING PAGES* ---

1. Claims 1-6 are under consideration.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US Patent 5,736,137)

Anderson et al. teach administration of chimeric antiCD20 antibody and radiolabelled antiCD20 for the treatment of B cell lymphoma (see column 5). Anderson et al. teach the chimeric antiCD20 antibody RITUXAN (eg. the antibody formerly known as C2B8, see Examples). Anderson et al. teach the use of radiolabelled antiCD20 antibody followed by the administration of previously collected and purged autologous bone marrow or stem cells (see column 10). Anderson et al. teach that radiolabelled antiCD20 antibody can be administered followed by multiple treatments with C2B8 (see column 31). Anderson et al. do not teach the preamble of the method of claim 1 or in vitro purging of the administered bone marrow or stem cells using antiCD20 antibody. Regarding the use of antiCD20 antibody for in vitro purging of the administered bone marrow or stem cells, a routineer would have performed said step in view of the teachings of Anderson et al. that antiCD20 can be used to effectively remove CD20 positive cells (see column 8). Regarding in vivo purging of the bone marrow or stem cell transplant, Anderson et al. teach that radiolabelled antiCD20 antibody can be administered followed by multiple treatments with C2B8, wherein the bone marrow or stem cells would have been administered shortly after radiolabelled antibody therapy because the purpose of transplanting said cells is to reverse damage to hematopoietic precursor cells caused by the radiolabelled antibody. Regarding the in vivo administration of C2B8, a routineer would have administered said antibody within one month of administration of radiolabelled antiCD20 because Anderson et al. teach that treatment with radiolabelled antiCD20 renders tumors more susceptible to C2B8 treatment . Regarding the preamble of the method of claim 1, Anderson et al. teach administration of chimeric antiCD20 antibody and radiolabelled antiCD20 for the

treatment of B cell lymphoma and the use of bone marrow or stem cell transplants. In view of the disclosed therapeutic effect of antiCD20 treatment, it would have been obvious that the instant treatment would reduce the risk of relapse in a patient receiving bone marrow or stem cells for treatment of lymphoma. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Anderson et al. teach administration of chimeric antiCD20 antibody and radiolabelled antiCD20 for the treatment of B cell lymphoma and use of radiolabelled antiCD20 antibody followed by the administration of previously collected and purged autologous bone marrow or stem cells, while based on the disclosed therapeutic effect of antiCD20 treatment, it would have been obvious that the instant treatment would reduce the risk of relapse in a patient receiving bone marrow or stem cells for treatment of lymphoma.

4. No claims are allowed.

5. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1644